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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,593	02/15/2002	Ellen M. Heath	GISM-P01-011	9392

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EXAMINER
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ART UNIT	PAPER NUMBER
1637	4

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,593	HEATH ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46 and 48-65* is/are rejected.

7)☒ Claim(s) *47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-65 are pending and are considered for examination except for claim 47.

2. The instant application has filing date as February 15, 2002 and claims no priority date.

Specification

3. The specification is objected because of the following informalities:

(i) a typographical error in claim 2, that is DNA is typed as DN;

(ii) The use of the trademark Puregene® has been noted in this application (see at least on page 12, line 21, page 26, claim 8). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

(iii) Claim 47 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claim 47 is a dependent claim of the claim 45. Claim 47 is confusing because the preamble of claim 45 is drawn to whole blood, likewise the recitation of the biological sample in claim 45 lacks antecedent basis. Accordingly it is unclear what biological sample claim 47 encompasses.

(iv) Claim 48 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 45. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one

claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 8, 18, 29, 39, 50, and 60 contains the trademark/trade name Puregene®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the reagents for the isolation of DNA and, accordingly, the identification/description is indefinite.

B. Claim 4, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites " biological sample is a virus", which is indefinite and unclear because it is not clear whether the biological sample consists only of virus or a virus is isolated from a biological sample comprising said virus. Amendment to recite the specific biological sample would obviate the rejection.

C. Claim 45 recites the limitation "biological sample" in isolating DNA from a whole blood sample. There is insufficient antecedent basis for this limitation in the claim. Claim 45 is limited to whole blood sample and not a biological sample. If this limitation refers to whole blood sample, the dependent claim 47 is confusing because the method steps of claim 45 appear to be drawn to a whole blood sample and not to bone marrow sample. Further the dependent claim 46 is also confusing because if the biological sample is selected from body fluids, the method steps of claim 45 appear to be drawn to whole blood and not to body fluids in claim 46. Amendment to specify the sample would obviate the rejection.

D. Claims 1-46, 48-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant independent claims 1-2, 24, and 45 recite a term "physically" in the context of separating the DNA, which is indefinite and unclear. It is not clear whether physically refers to by hand, by centrifugation, by electrophoresis, by elution or by chromatographic separation. Amendment to specify the separation means would obviate the rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-2, 7-9, 17-24, 28-30, 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath et al. (Arch. Pathol. Lab. Med., Vol. 125, pp. 127-133, January 2001).

With reference to the instant claims 1-2 and 24, Heath et al. teach a method for isolating DNA from a biological sample comprising cells wherein Heath et al. disclose that the method comprises (a) separating the biological material comprising DNA (buccal cells) from remainder of the biological sample (see page 127, column 2, paragraph 2, lines 1-5, page 128, table 2, steps 1-2); (b) contacting the separated biological material comprising DNA with a hypertonic high salt solution (mouthwash) so as to form a suspension of said biological material containing DNA (see page 127, column 2, paragraph 2, lines 1-5, page 128, table 1, table 2, steps 1-2, column 2, paragraph 1); (c) contacting the suspension with a cell lysis reagent from Puregene® DNA tissue kit to release DNA from non-DNA components (see page 128, column 2, paragraph 1, lines 1-23, table 2, steps 2-4); (d) physically separating DNA by precipitation (eluting with isopropanol) to yield isolated DNA (see page 128, column 2, paragraph 1, lines 23-27, page 129, column 1, lines 1-12, table 2, step 5).

With reference to the instant claims 7-9, 17-22, 28-30, 38-43, Heath et al. teach that the method comprises (i) non-DNA biological component comprises protein (see page 128, column 2, paragraph 1); (ii) hypertonic, high salt reagent as Puregene® protein precipitation solution from Gentra systems, Inc. (see page 128, column 2, paragraph 1, lines 1-2 table 1); (iii) high salt reagent comprises salt in an amount effective to precipitate proteins out of lysate (see page 128, table 2, step 4, column 2, paragraph 1, lines 1-23); (iv) lysis reagent comprises RNase solution (see page 128, column 2, paragraph 14-17); (v) separating the DNA comprises precipitating non-DNA components from lysate by centrifugation (see page 128, table 2, step 4); separating DNA

from lysate comprises contacting with an alcohol to precipitate DNA and a wash solution (see page 128, table 2, step 5).

With reference to the instant claims 23, and 44, Heath et al. also disclose that the method comprises (i) treating the isolated DNA with a hydration reagent (see page 128, table 2, step 6). Thus the disclosure of Heath et al. meets the limitations in the instant claims.

B. Claims 1-3, 6-7, 9-13, 19-22, 24-25, 27-28, 30-34, 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (USPN. 5,596,092).

With reference to the instant claims 1-2, and 24, Schneider teaches a method for isolating DNA from a biological sample comprising whole blood cells (bone marrow cells) wherein Schneider discloses that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample (see column 1, lines 65-67, column 4, lines 16-21, column 5, lines 23-25); (b) contacting the separated biological material comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 2, lines 1-16); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 2, lines 16-25); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 2, lines 52-67).

With reference to the instant claims 3, 6-7, 9-13, 25-28, 30-34, Schneider teaches that the method comprises (i) biological sample selected from whole blood cells, cultured animal cells (see column 1, lines 65-67, column 4, lines 16-21, column 5, lines 23-25); (ii) non-DNA biological component comprises protein (see column 2, 16-25); (iii) high salt reagent comprises salt in an amount effective to precipitate proteins out of lysate (see column 2, lines 16-25); salt includes soluble sodium, ammonium, lithium or potassium concentration of the salts range from

above 0.5M to 4M (see column 2, lines 12-16); lysis reagent comprises a detergent (see column 2, lines 4-16).

With reference to the claims 19-22, 40-43, Schneider teaches that (i) separating the DNA comprises precipitating non-DNA components from lysate by centrifugation (see column 2, lines 52-67); (v) separating DNA from lysate comprises contacting with an alcohol to precipitate DNA and a wash solution (see column 3, lines 43-46). Thus the disclosure of Schneider meets the limitations in the instant claims.

C. Claims 1-3, 6-7, 9-16, 19-25, 27-28, 30-37, 40-46, 48, 49, 51-58, and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray et al. (USPN. 5,777,098).

With reference to the instant claims 1-2, 24, and 45, Gray et al. teach a method for DNA purification wherein Gray et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample which includes contacting whole blood with a red blood lysis solution and separating white blood cells comprising DNA (see column 2, lines17-25, column 3, lines 1-21, column 7, lines 1-12); (b) contacting the separated biological material (white blood cells) comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 4, lines 48-58); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 4, lines 34-36); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 5, lines 1-11).

With reference to the instant claims 3, 6-7, 9-16, 19-25, 27-28, 30-37, 40-46, 48, 49, 51-58, 61-65, Gray et al. teach that the method comprises (i) biological sample includes whole, blood cells, animal and plant tissue and cultured tissue cells (see column 2, lines 60-67, column

6, lines 65-67, column 7, lines 1-3, lines 46-50, column 8, lines 36-41); (ii) high salt reagent comprises salts such as sodium, ammonium or potassium salts in an amount effective (ranging from about 0.1 to about 12M) to precipitate proteins out of lysate (see column 4, lines 48-58); (iii) lysis reagent comprises anionic detergent of sodium dodecyl sulfate (sodium lauryl sulfate) in a concentration from about 0.1% to about 20% w/v (see column 4, lines 36-42); physically separating the DNA from the lysate comprises physically separating non-DNA components from the lysate without use of any additional reagents to yield DNA and is facilitated by centrifugation which further includes an alcohol, a wash solution and a rehydration reagent (see column 5, lines 1-26). Thus the disclosure of Gray et al. meets the limitations in the instant claims.

D. Claims 1-4, 9-16, 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Henco et al. (USPN. 5, 057,426).

With reference to the instant claims 1-2, and 24, Henco et al. teach a method for isolating DNA from a biological sample wherein Henco et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample (see column 11, lines 53-59, column 12, lines 20-25); (b) contacting the separated biological material comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 10, lines 30-40, column 12, lines 26-32); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 11, lines 60-63); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 11, lines 64-68, column 12, lines 1-15).

With reference to the instant claims 3-4, 9-16, 30-37, Henco et al. also teach that (i) the method comprises biological material comprising bacterial cells, viruses, vegetable and animal

tissue cells (see column 5, lines 10-21); lysis reagent comprises sodium dodecyl sulfate an anionic detergent greater than 0.1% w/v (see column 11, lines 60-63); (ii) high salt solution comprises sodium salts (3M sodium acetate) (see column 11, lines 63-67). Thus the disclosure of Henco et al. meets the limitations in the instant claims.

E. Claims 1-3, 5-6, 13-16, 19-21, 24-28, 34-37, 40-42, 55-58, 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Fairman (Pub No. US 2002/0068280).

Fairman teaches a method for isolating DNA from a whole blood wherein Fairman teaches that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample which includes contacting whole blood with a red blood lysis solution and separating white blood cells comprising DNA (see page 2, paragraph 0022, lines1-17, instant claims 1-3, 6-7, 24-25, 27 and 45); (b) contacting the separated biological material (white blood cells) comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see page 2, paragraph 0022, lines 12-15); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see page 2, paragraph 0022, lines 15-18, instant claims 19, 40); (d) physically separating DNA by centrifugation to yield isolated DNA (see page 2, paragraph 0022, lines 18-27, instant claims 20, 41). Fairman also teach that the method comprises non-blood fluids such as bone marrow sample (see page 3, paragraph 0024, lines 1-3, instant claims 5, 26, 34-35); anionic detergent in lysis reagent (see page 3, paragraph 0031, lines 1-6, instant claims 13-14); detergent comprise sodium dodecyl sulfate (1g. SDS/liter) (see page 2, paragraph 0022, lines 15-18, instant claim 13-16, 35-37, 56-58); precipitating isolated DNA with isopropanol (see page 5,

column 2, lines 60-62, instant claims 21, 42, 63). Thus the disclosure of Fairman meets the limitations in the instant claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 50; 59-60, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (USPN. 5,777,098). in view of Heath et al. (Arch. Pathol. Lab. Med., Vol. 125, pp. 127-133, January 2001).

Gray et al. teach a method for DNA purification wherein Gray et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample which includes contacting whole blood with a red blood lysis solution and separating white blood cells comprising DNA (see column 2, lines17-25, column 3, lines 1-21, column 7, lines 1-12); (b) contacting the separated biological material (white blood cells)

comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 4, lines 48-58); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 4, lines 34-36); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 5, lines 1-11). Gray et al. also teach that the method comprises (i) biological sample includes whole, blood cells, animal and plant tissue and cultured tissue cells (see column 2, lines 60-67, column 6, lines 65-67, column 7, lines 1-3, lines 46-50, column 8, lines 36-41); (ii) high salt reagent comprises salts such as sodium, ammonium or potassium salts in an amount effective (ranging from about 0.1 to about 12M) to precipitate proteins out of lysate (see column 4, lines 48-58); (iii) lysis reagent comprises anionic detergent of sodium dodecyl sulfate (sodium lauryl sulfate) in a concentration from about 0.1% to about 20% w/v (see column 4, lines 36-42); physically separating the DNA from the lysate comprises physically separating non-DNA components from the lysate without use of any additional reagents to yield DNA and is facilitated by centrifugation which further includes an alcohol, a wash solution and a rehydration reagent (see column 5, lines 1-26). However Gray et al. did not teach Puregene® protein precipitation solution and RNase.

Heath et al. teach a method for isolating DNA from a biological sample comprising buccal cells wherein Heath et al. disclose that the method comprises (i) Puregene® protein precipitation reagent which uses nontoxic agents (see page 128, column 2, paragraph 1, lines 1-2 table 1); (ii) lysis reagent with RNase solution (see page 128, column 2, paragraph 1, lines 15-17, table 2, step 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of isolating DNA from a biological

sample as taught by Gray et al. with nontoxic Puregene® protein precipitation solution as taught by Heath et al. to achieve expected advantage of developing a sensitive and enhanced method because Heath et al. suggests that "the method uses nontoxic reagents, simple to perform and yields high quality DNA suitable for southern blotting, amplification, archiving, and other molecular genetic applications " (see page 127, column 1, paragraph 2, lines 5-6, column 2, lines 1-3). Further, it is noted that the method of Gray et al. does not require RNase, however, it would have been prima facie obvious to one of ordinary skill in the art to include RNase to ensure that all RNA was degraded. The use of RNase in DNA isolation and purification assays was well known in the art at the time the invention was made, for the purpose of degrading unwanted or contaminating RNA as exemplified by the teaching of Heath et al.

It is further noted that selection of parameters such as RNase for routine optimization are explicitly recognized in Heath et al. As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the RNase treatment performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

An ordinary practitioner would have been motivated to combine the method of Gray et al. with the limitations such as the Puregene® cell protein precipitation solution, and RNase of Heath et al. because incorporating these limitations taught by Heath et al. in combination with the method of Gray et al. would reduce the use of toxic reagents, reduce the contaminating

RNA and improve the quality and yield of the DNA.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
July 14, 2003

JEHANNE SOUAYA
~~PATENT~~ EXAMINER
Primary

Jehanne Souaya
July 14, 2003